UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming

Products Liability Litigation

MDL No. 15-2666 (JNE/FLN)

This Document Relates To: All Actions

DECLARATION OF BENJAMIN W. HULSE IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS'

MOTION FOR LEAVE TO AMEND MASTER LONG FORM

AND SHORT FORM

COMPLAINTS TO ADD CLAIM

FOR PUNITIVE DAMAGES

Benjamin W. Hulse, being first duly sworn, deposes and declares:

I am one of the attorneys representing Defendants 3M Company and Arizant Healthcare Inc. in connection with the above-referenced matter. I make this declaration in support of Defendants' Opposition to Plaintiffs' Motion for Leave to Amend Master Long Form and Short Form Complaints to Add Claim for Punitive Damages.

- 1. Attached as Defendants' Exhibit 1 is a true and correct copy of a document entitled HotDog Patient Warming, Augustine Temperature Management, "Refund Guarantee," previously available on Augustine's website at http://www.hotdog-usa.com/guarantee.php (July 12, 2012).
- 2. Attached as Defendants' Exhibit 2 is a true and correct copy of Sikka RS, et al. Forced Air Warming Devices in Orthopaedics: A Focused Review of the Literature. *The Journal of Bone & Joint Surgery* 96.24 (2014): e200.

- 3. Attached as Defendants' Exhibit 3 is a true and correct copy of Kellam MD, et al. Forced-air warming devices and the risk of surgical site infections. *AORN Journal* 98.4 (2013): 353-69.
- 4. Attached as Defendants' Exhibit 4 is a true and correct copy of Forced-Air Warming and Surgical Site Infections: Our Review Finds Insufficient Evidence to Support Changes in Current Practice. ECRI Institute, Guidance Article (April 2013): 122-25.
- 5. Attached hereto as Defendants' Exhibit 5 is a true and correct copy of excerpts from the deposition testimony of Mark Albrecht, taken on October 7, 2016 and November 12, 2016.
- 6. Attached as Defendants' Exhibit 6 is a true and correct copy of Zink R. et al., "Convective warming therapy does not increase the risk of wound contamination in the operating room." *Anesthesia & Analgesia* 76.1 (1993):50-53.
- 7. Attached as Defendants' Exhibit 7 is a true and correct copy of Huang J.K.C. et al., "The Bair Hugger patient warming system in prolonged vascular surgery: an infection risk?" *Critical Care* 7.3 (2003): R13-R16.
- 8. Attached as Defendants' Exhibit 8 is a true and correct copy of Moretti, B., et al., Active warning systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or vector of infection, *Journal of Hospital Infection* 73 (2009):73:58-63.

- 9. Attached as Defendants' Exhibit 9 is a true and correct copy of Hall AC and Teenier T. Bair Hugger Warmer Does Not Increase Microbial Contamination in the Operating Room. PGA poster presentation (1991).
- 10. Attached as Defendants' Exhibit 10 is a true and correct copy of Dirkes WE and Minton WA. Convection warming in the operating room: Evaluation of bacterial spread with three filtration levels. *Anesthesiology* 81.3A (1994): A562 (DX10).
- 11. Attached as Defendants' Exhibit 11 is a true and correct copy of Avidan MS et al., Convection warmers: not just hot air. *Anaesthesia* (1997): 1073-76.
- 12. Attached as Defendants' Exhibit 12 is a true and correct copy of Oguz R. et al., Airborne bacterial contamination during orthopedic surgery: A randomized controlled pilot trial. *Journal of Clinical Anesthesia* 38 (2017): 160-164.
- 13. Attached as Defendants' Exhibit 13 is a true and correct copy of Association for Professionals in Infection Control and Epidemiology, Guide to the Elimination of Surgical Site Infections (2010) (DX13).
- 14. Attached as Defendants' Exhibit 14 is a true and correct copy of Sessler D., Non-pharmacologic Prevention of Surgical Wound Infection. *Anesthesiol Clin.* 24.2 (2006): 279-97.
- 15. Attached hereto as Defendants' Exhibit 15 is a true and correct copy of excerpts from the Rule 30(b)(6) deposition of 3M employee Albert Van Duren.
- 16. Attached as Defendants' Exhibit 16 is a true and correct copy of a test report prepared by BIOTEST Laboratories (3MBH00761308-309). This document is filed under seal.

- 17. Attached as Defendants' Exhibit 17 is a true and correct copy of a test report prepared by BIOTEST Laboratories (3MBH00761310-311). This document is filed under seal.
- 18. Attached Defendants' Exhibit 18 is a true and correct copy of an excerpt from the Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection held on August 1, 2013.
- 19. Attached as Defendants' Exhibit 19 is a true and correct copy of ASHRAE, HVAC Design Manual for Hospitals and Clinics (2d ed.). ASHRAE is the American Society of Heating, Refrigerating and Air-Conditioning Engineers.
- 20. Attached as Defendants' Exhibit 20 is a true and correct copy of a Patient Warming Formal Test Report dated August 25, 2016. This document is filed under seal.
- 21. Attached as Defendants' Exhibit 21 is a true and correct copy of a publication of the United States Environmental Protection Agency entitled "Residential Air Cleaners: A Summary of Available information" (Revised Au. 2009). At page 11, EPA summaries minimum efficiency reporting value (MERV) parameters for various applications, including general surgery.
- 22. Attached hereto as Defendants' Exhibit 22 is a true and correct copy of excerpts from the deposition of former 3M and Arizant employee David Westlin on December 16, 2016.
- 23. Attached as Defendants' Exhibit 23 is a true and correct copy of excerpts from the deposition of former Arizant CEO Gary Maharaj on January 18, 2017.

- 24. Attached as Defendants' Exhibit 24 is a true and correct copy of a document entitled "Ion Armour Thoughts." This document is filed under seal.
- 25. Attached as Defendants' Exhibit 25 is a true and correct copy of excerpts from the deposition testimony of former 3M employee Winston Tan, taken on March 10, 2017.
- 26. Attached as Defendants' Exhibit 26 is a true and correct copy of excerpts from the deposition testimony of former 3M and Arizant employee Gary Hansen, taken on November 2, 2016.
- 27. Attached as Defendants' Exhibit 27 is a true and correct copy of excerpts from the deposition testimony of Dr. Daniel Sessler of Cleveland Clinic, taken on January 11, 2017.
- 28. Attached as Defendants' Exhibit 28 is a true and correct copy of excerpts from the deposition of former 3M employee Jana M. Stender on December 9, 2016.
- 29. Attached as Defendants' Exhibit 29 is a true and correct copy of excerpts from the deposition of 3M employee Troy Bergstrom on November 18, 2016.
- 30. Attached as Defendants' Exhibit 30 is a true and correct copy of a letter from 3M Company to the United States Food and Drug Administration dated December 1, 2016.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 11th day of May, 2017.

s/ Benjamin W. Hulse

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